Prosthesis for repairing heart wall defects

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Abstract of **FR2714284**

The prosthesis consists of a circular component made from a supple material with a shape memory effect, able to occupy three different positions. In the first position (2) it is extended lengthwise to form a small cylinder which can be introduced through a catheter, with its proximal end closed by a valve (4). In a second position the two compartments (8,10) are inflated separately so that they are deployed on opposite sides of the ruptured wall, while in the third position the compartments are squeezed together to form a double patch on the wall. The prosthesis has a radio-opaque marker (6) between the two compartments which allows its progress through the patient's body to be monitored.

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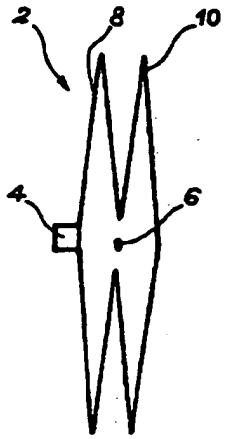
(54) Prothèse pour la fermeture des ruptures des parois cardiaques, notamment des ruptures septales interventriculaires.

(57) Prothèse pour la fermeture des ruptures septales interventriculaires, caractérisée en ce qu'elle comporte une pièce de matériau souple, ayant un axe de symétrie de révolution, réalisée dans un matériau doué d'une mémoire de forme, susceptible de prendre trois positions différentes, à savoir:

- une première position (2) étirée en longueur selon l'axe, logeable dans un cathéter guide d'introduction, l'extrémité proximale de ce petit cylindre étant fermée par une valve (4);
- une deuxième position, inscrite dans la mémoire de forme du matériau, obtenue par gonflage et consistant en un ballon double, dont les deux compartiments (8, 10) se déploient à la manière d'un "yoyo";
- une troisième position obtenue par mise en dépression de l'intérieur du ballon double, dans laquelle les deux compartiments du ballon se contractent en enserrant les parois de l'ouverture qu'ils colmatent ainsi à la manière d'un "patch" double.



FR 2 714 284 - A1

PROTHESE POUR LA FERMETURE DES RUPTURES DES PAROIS CARDIAQUES, NOTAMMENT DES RUPTURES SEPTALES INTERVENTRICULAIRES

La présente invention se rapporte aux techniques de fermeture par voie percutanée des parois cardiaques comportant une ouverture congénitale ou acquise anormale.

Plus spécialement, elle s'applique aux communications interventriculaires et interauriculaires congénitales du coeur et, également aux ruptures accidentelles du septum, qui alors qu'il sépare normalement les ventricules droit et gauche, vient parfois à se rompre, consécutivement à un infarctus du myocarde.

Dans la suite du présent texte on se référera uniquement à ce dernier cas, à la fois pour des raisons de simplicité de l'exposé et parce que c'est le domaine le plus important d'application de l'objet du brevet, mais il doit être bien entendu que ceci n'implique aucune limitation de ce domaine d'application qui englobe au contraire la fermeture par voie percutanée de toute paroi interne du coeur comportant une ouverture congénitale ou acquise anormale.

La rupture septale post-infartus du myocarde, sans être très fréquente (moins de 1% des infarctus du myocarde), est une pathologie redoutable par son évolution spontanée et la lourdeur de sa prise en charge médico-chirurgicale. Elle place très régulièrement les cardiologues et les chirurgiens devant de difficiles problèmes thérapeutiques.

Un exposé de l'état de la technique - physiologie et traitement - dans ce domaine sera fait maintenant en se référant aux principales publications connues, citées à la fin du présent mémoire descriptif et référencées de 1 à 14.

Les ruptures septales interventriculaires secondaires à des infarctus du myocarde sont grevées d'une évolution spontanée très défavorable - 90 à 100% de décès en l'absence de cure chirurgicale (1-3) -, et d'une mortalité post-opératoire élevée - 10% à 45% suivant les séries, le plus souvent entre 35 et 40% (1-9) -.

Ce surcroît de mortalité par rapport aux infarctus du myocarde "standard" est pour une grande part liée au shunt aigu gauche-droit, qui, par mise en communication du coeur droit et du coeur gauche, provoque un bas débit systémique et une hypertension artérielle pulmonaire avec une insuffisance cardiaque droite. L'obturation temporaire (4 jours) par un ballon "classique" monté par voie percutanée, effectuée par une équipe japonaise démontre bien l'amélioration hémodynamique spectaculaire ainsi obtenue ; dans ce cas la chirurgie a pu être ainsi réalisée secondairement dans de bonnes conditions (10).

Les facteurs prédictifs de la mortalité opératoire les plus souvent retrouvés sont : le choc cardiogénique, un court délai entre la constitution du défect septal et la chirurgie, un infarctus ventriculaire droit, des lésions pluritronculaires, des pressions droites moyennes basses, le diabète (1-9).

Cette pathologie touche des patients mono, bi- et tritronculaires en proportion sensiblement égale. La mortalité immédiate ne serait pas liée à la réalisation de pontages aorto-coronariens (3, 7) ; seule une étude démontre que le pontage de la coronaire droite améliorerait la survie immédiate (2). Par contre les pontages associés à la correction de la rupture septale amélioreraient la survie à long terme (8).

Enfin les patients qui survivent à l'intervention ont une bonne espérance de vie et un

statut fonctionnel le plus souvent satisfaisant (1, 3, 6, 7).

Anatomiquement ces ruptures septales sont caractérisées par :

- leur aspect macroscopique : contrairement aux communications interventriculaires congénitales, bien délimitées au sein d'un tissu myocardique normal, ces ruptures septales post-infactus sont des fentes, des déchirures siègeant dans une partie de myocarde infarcie, molle et fragile. L'orifice est le plus souvent unique mais parfois il en existe plusieurs qui sont alors tous très proches. La taille de ces ruptures septales est de 1,8 $\pm$ 0,8 cm avec des valeurs extrêmes allant de 0,8 à 2,3 cm.

- leur situation : celle-ci est variable suivant la localisation de l'infarctus. La communication interventriculaire peut siéger sur le septum basal, moyen ou apical et peut être antérieure, médiane ou inféro-postérieure. Elles sont en fait plus rarement basales (10). Les ruptures septales localisées trop près d'un appareil valvulaire ou siégeant dans la chambre de chasse pulmonaire ou aortique (localisation basale) pourraient être des contre-indications à l'utilisation de la méthode objet du brevet.

- L'évolution du tissu myocardique autour de la communication interventriculaire : si le patient survit, le myocarde concerné se fibrose et devient donc plus ferme, comme toute paroi cardiaque infarcie. Les chirurgiens préfèrent intervenir à ce stade car la suture des "patchs" de fermeture de communication interventriculaire est alors plus aisée.

<u>Etat actuel des fermetures par voie percutanée des parois intra-cardiaques</u> :

A notre connaissance il n'y a jamais eu d'occlusion définitive de rupture septale post-infarctus

ayant fait l'objet de publication. Par contre il existe des matériaux utilisés pour la fermeture par voie percutanée des communications interauriculaires et interventriculaires congénitales qui sont tous dans leur phase expérimentale. Ce sont surtout les communications inter-auriculaires congénitales qui ont fait l'objet d'occlusions par voie percutanée. Il s'agit de systèmes développés par le Docteur SIDERIS de l'Hôpital d'Athènes et par la Société BARD.

Pour le premier il s'agit d'un patch de tissu retenu par une agrafe et dans le deuxième cas d'un double patch de Dacron® déployé par des bras métalliques placés de part et d'autre de l'orifice à obturer. Ce dernier système appelé "clams-shell" en terminologie anglo-saxonne a aussi été utilisé dans la fermeture de communnications interventriculaires congénitales dans le cadre de malformations cardiaques complexes le plus souvent avant une chirurgie palliative ou corrective, mais aussi après ce type de chirurgie pour occlure des communications interventriculaires résiduelles (12, 13). Enfin, une toute petite série de six patients a fait l'objet de l'occlusion de communications interventriculaires péri-membraneuses par le système d'ombrelle de Rashkind utilisé habituellement dans la fermeture des canaux artériels (14).

Ces différentes prothèses présentent des inconvénients sérieux qui n'ont pas permis jusqu'à ce jour leur développement généralisé et les ont conduites à rester plutôt au stade expérimental. En effet, leur pose, à l'aide de systèmes d'agrafes ou de bras métalliques déployés, n'est pas sans nécessiter des contraintes mécaniques problématiques sur les parois forcément fragiles de la rupture, sans garantir pour autant de façon constante leur bonne tenue. Par

ailleurs, la qualité de l'étanchéité qu'elles procurent est en partie aléatoire.

L'occlusion précoce (dès le diagnostic fait, avant toute dégradation hémodynamique) par une méthode non chirurgicale, peu traumatisante de la rupture septale, doit permettre une réduction notable des décès observés dans cette pathologie. C'est pourquoi la présente invention a pour objet une prothèse implantable par voie percutanée pour la fermeture de ces ruptures septales interventriculaires qui permet de s'affranchir de la majeure partie des inconvénients rappelés précédemment de l'art antérieur.

Cette prothèse pour l'occlusion par voie percutanée des ouvertures de parois du coeur est caractérisée en ce qu'elle comporte une pièce de matériau souple, ayant un axe de symétrie de révolution, réalisée dans un matériau doué d'une mémoire de forme, susceptible de prendre trois positions différentes, à savoir :

- une première position étirée en longueur selon l'axe, dans laquelle la pièce de matériau souple adopte la forme d'un petit cylindre fermé, creux et allongé, logeable dans un cathéter guide d'introduction, l'extrémité proximale de ce petit cylindre étant fermée par une valve de communication entre l'intérieur du cylindre précédent et l'extérieur ;

- une deuxième position, inscrite dans la mémoire de forme du matériau, obtenue par gonflage de l'intérieur du cylindre précédent au travers de la valve et consistant en un ballon double, dont les deux compartiments se déploient à la manière d'un "yoyo" dans une direction perpendiculaire à l'axe de symétrie, chacun des compartiments étant destiné à être appliqué contre l'une des faces de l'ouverture à colmater ;

- une troisième position obtenue par mise

en dépression de l'intérieur du ballon double, dans laquelle les deux compartiments du ballon se contractent en enserrant les parois de l'ouverture qu'ils colmatent ainsi à la manière d'un patch double.

Selon une caractéristique additionnelle, certaines zones de la prothèse, dont la partie médiane, située entre les deux compartiments du ballon, sont munies de marqueurs radio-opaques qui permettent de suivre l'évolution de la prothèse et sa sortie du cathéter lors de son implantation dans le corps humain.

Les trois positions précédemment définies de la prothèse correspondent chacune à une phase de la mise en place de celle-ci par voie percutanée. En effet :

- la première position ou position "étirée" est utilisée pour introduire et glisser le ballon dans le cathéter-guide d'introduction par voie percutanée. La position étirée dans ce cathéter est maintenue par un fil raidisseur de 0,3 mm dont l'extrémité est mousse ;

- la deuxième position ou position gonflée permet le positionnement du ballon. Le compartiment distal est d'abord sorti de la gaine, introduit au travers de l'orifice à fermer, puis gonflé et mis en place contre la face distale de cet orifice. Le compartiment proximal est alors gonflé et mis en place contre la face proximale de l'orifice, les parois de l'orifice étant ainsi insérées entre les deux compartiments du ballon. Le raidisseur est progressivement retiré au fur et à mesure de la mise en place du ballon, avant l'inflation de chaque compartiment. Au cours de ces diverses opérations, l'emplacement du ballon dans son cathéter guide et par rapport à la paroi à obturer est suivie par observation de l'emplacement des marqueurs opaques aux rayons X ;

- la troisième position ou position en dépression est obtenue en mettant les deux compartiments du ballon en dépression au travers de la valve, ce qui provoque le placage des deux compartiments contre la paroi à obturer, à la manière d'un patch double et confère à la prothèse la stabilité par serrage l'un contre l'autre des deux demi-patch constitués par chaque compartiment du ballon.

Au cours des deux phases précédentes, le gonflage du ballon et sa mise en dépression sont réalisés par injection et retrait à l'intérieur du ballon d'un liquide opaque aux rayons X, à l'exclusion de tout composé gazeux dont l'apport dans le sang en cas de fuite accidentelle du ballon serait catastrophique pour le patient.

Une fois le ballon ainsi mis en dépression, il occupe sa position définitive et, après une période de surveillance de quelques heures, au cours de laquelle un système de sécurité permet éventuellement sa récupération d'urgence, il peut être laissé en place.

La prothèse objet de l'invention répond parfaitement aux contraintes fixées pour un appareil de ce genre qui doit :

1. Avant sa mise en place :

- avoir un diamètre maximal de 3 mm en position repliée afin de pouvoir être glissé dans une gaine de diamètre 12 French, voir 11 French (1 French = 0,33 mm),
- pouvoir glisser dans la gaine,
- être stérile.

2. Lors de la mise en place :

- pouvoir se déplier de façon prévisible et constante suivant une forme pré-établie,
- être appliqué et mis en place au bon endroit,
- ne pas provoquer de traction sur le septum (tissu myocardique mou et fragile),

- être largué avec si possible un système de sécurité dont l'objectif est de pouvoir récupérer le patch lors des 24 premières heures si cela s'avère nécessaire, et aussi d'éviter une éventuelle migration précoce de ce patch.

3. Après la mise en place :

- être stable,

- être immédiatement continent afin d'obtenir d'emblée le bénéfice hémodynamique,

- être si possible non thrombogène (si cette condition ne peut pas être remplie, une anti-coagulation, tout comme pour les valves mécaniques, peut être effectuée).

Les deux avantages essentiels de ce patch sont :

- l'absence de traction sur le septum interventriculaire pour l'appliquer ;

- son maintien par le phénomène d'aspiration, sans point de suture sur le septum, qui est en règle générale très friable.

De toute façon, l'invention sera mieux comprise en se référant à la description qui suit d'un exemple de réalisation et de mise en oeuvre de la prothèse objet de l'invention, description qui sera faite en se référant aux figures 1 à 7 ci-jointes données à titre descriptif et non limitatif, sur lesquelles on voit :

- sur la figure 1, la prothèse dans sa position étirée,

- sur la figure 2, la prothèse gonflée, avec son ballon à deux compartiments,

- sur la figure 3, la prothèse en dépression,

- sur la figure 4, la mise en place d'une gaine contenant la prothèse devant une rupture septale d'un coeur humain,

- sur la figure 5, la mise en place du compartiment distal de la prothèse après gonflement,

- sur la figure 6, la mise en place du compartiment proximal de la prothèse également gonflé,

- sur la figure 7, la mise en déflation du ballon.

Sur la figure 1, on voit la prothèse 2 sous la forme étirée, constituée d'un petit cylindre de matériau souple doué de mémoire de forme, ici en l'occurence celle d'un ballon double à deux compartiments (figure 2). Dans un exemple de réalisation, donné à titre non limitatif, la longueur a du ballon étiré est de 92 mm et son diamètre extérieur est c = 3 mm. Conformément à l'invention, il est terminé sur sa face proximale par une valve 4, d'un type en soi connu, donc la longueur b = 3 mm. Au centre de la prothèse, se trouve l'un des marqueurs 6, opaque aux rayons X.

Sur la figure 2, on voit la prothèse 2 en position gonflée, composée de son ballon à deux compartiments 8 et 10, destinés à être placés, comme on le verra plus loin, pour le compartiment proximal 8 dans le ventricule droit et pour le compartiment distale 10, dans le ventricule gauche d'un coeur dont on cherche à obturer une communication interventriculaire présente dans le septum. Le ballon gonflé 2 a la forme générale d'un "yoyo" dont les compartiments ont un rayon de l'ordre de 23 mm. La zone centrale du "yoyo" a un diamètre voisin de 5 mm.

La figure 3 montre le même ballon, muni des mêmes éléments, mais en position rétractée après mise en dépression au travers de la valve 4. C'est la position définitive du patch double qui permet l'occlusion de la rupture septale interventriculaire et la stabilité du patch, enserrant la paroi septale

entre les deux demi-patch, constitué chacune d'un compartiment du ballon aplati par la dépression.

En se référant aux figures 4 à 7, on va décrire ci-après les différentes étapes de la mise en place de la prothèse, objet de l'invention. Sur ces figures schématiques, on a représenté un coeur humain ouvert et vu de face, sur lequel on reconnaît le myocarde 12, les oreillettes droite et gauche 14 et 16 et les ventricules droit 18 et gauche 20, séparés par le septum 22, lequel comporte précisément une ouverture 24 consécutive à un infarctus et que l'on veut obturer à l'aide de la prothèse objet de l'invention. Les veines cave supérieure 26 et inférieure 28 ont également été représentées.

a) Phase préliminaire

Dans une phase préliminaire on effectue d'abord une ponction artérielle de diamètre 6 French pour mettre en place l'extrémité d'une sonde en "queue de cochon" dans le ventricule gauche 20 et réaliser une ventriculographie en double incidence afin de localiser l'emplacement de la communication interventriculaire 24. En fonction de cet emplacement, une ponction jugulaire droite ou fémorale permet ensuite la mise en place d'un introducteur de diamètre 11 French et la montée d'une gaine 30 de 11 French dont l'extrémité 32 est placée devant la communication interventriculaire 24. L'extrémité 32 est façonnée à la vapeur d'eau sur la table opératoire en fonction de l'emplacement de la communication interventriculaire.

b) Montée et placement du patch :

Une sonde de diamètre 3F est introduite dans la valve 4 de la prothèse. Un fil raidisseur de 0,30 mm à extrémité mousse est glissé dans la sonde de diamètre 3F puis dans le ballon afin de le mettre en "position étirée".

La prothèse ainsi montée est introduite puis poussée dans la sonde-guide jusqu'à son extrémité par un cathéter pousseur de diamètre 9F (de même façon que pour un filtre cave). Le patch est sorti sur la moitié de sa longueur jusqu'à la zone de l'isthme entre les deux compartiments 8 et 10. Le raidisseur de 0,30 mm est alors retiré de la partie distale du patch qui est gonflé par une solution radio-opaque (mélange de sérum physiologique et de liquide de contraste iodé). Dans un premier temps (figure 5), seule la partie distale 10, libérée du guide prend sa forme, sur le versant ventriculaire gauche du septum à la manière d'un bouton au travers d'une boutonnière. Tout en retirant progressivement le guide de 0,30 mm, la gaine de diamètre 11F est retirée sur le pousseur (ce dernier étant en point fixe) ce qui libère la partie proximale 8 du ballon. Pendant cette manoeuvre le gonflement du patch est poursuivi jusqu'à ce qu'il prenne sa forme "position gonflée". Il a alors une forme de "yoyo" enserrant le septum interventriculaire (figure 6). Ensuite il est dégonflé et s'applique de part et d'autre du septum (figure 7) par simple dépression.

c) Larguage du patch :

En maintenant le pousseur en point fixe, la sonde 3F est tirée de la valve qui se referme.

Le cathéter pousseur et la gaine 11F sont retirés et le système de sécurité est laissé en place.

d) Le système de sécurité :

Il s'agit d'un simple fil en boucle dont la partie médiane est passée dans le patch, et l'autre extrémité est gardée à l'extérieur du patient, au travers de l'introducteur. Il suffit de couper le fil à l'extérieur puis de le tirer pour l'enlever. Le fil doit être fin, résistant à la traction et glissant.

e) Vérification :

Après 24 heures, il est possible de réaliser une vérification, soit par échocardiographie, soit par une nouvelle opacification ventriculaire gauche. Si le patch est continent, le système de sécurité est enlevé (le fil est coupé à l'extérieur du patient, et simplement tiré) puis l'introducteur veineux est retiré. Par contre si le patch n'est pas efficace ou n'est plus en place, ou encore provoque un effet secondaire il peut être retiré par traction et récupéré au niveau de l'introducteur veineux (au besoin en repassant un raidisseur de 0,30 mm pour l'étirer et le glisser au travers de l'introducteur).

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REVENDICATIONS

1. Prothèse pour la fermeture des ruptures (24) des parois cardiaques, notamment des ruptures septales interventriculaires consécutives à un infarctus, caractérisée en ce qu'elle comporte une pièce de matériau souple, ayant un axe de symétrie de révolution, réalisée dans un matériau doué d'une mémoire de forme, susceptible de prendre trois positions différentes, à savoir :

- une première position (2) étirée en longueur selon l'axe, dans laquelle la pièce de matériau souple adopte la forme d'un petit cylindre fermé, creux et allongé, logeable dans un cathéter guide d'introduction, l'extrémité proximale de ce petit cylindre étant fermée par une valve (4) de communication entre l'intérieur du cylindre précédent et l'extérieur ;

- une deuxième position, inscrite dans la mémoire de forme du matériau, obtenue par gonflage de l'intérieur du cylindre précédent au travers de la valve (4) et consistant en un ballon double, dont les deux compartiments (8, 10) se déploient à la manière d'un "yoyo" dans une direction perpendiculaire à l'axe de symétrie, chacun des compartiments étant destiné à être appliqué contre l'une des faces de l'ouverture (24) à colmater ;

- une troisième position obtenue par mise en dépression de l'intérieur du ballon double, dans laquelle les deux compartiments du ballon se contractent en enserrant les parois de l'ouverture qu'ils colmatent ainsi à la manière d'un "patch" double.

2. Prothèse selon la revendication 1, caractérisée en ce qu'elle est munie, à divers endroits et notamment dans la zone axiale comprise entre les deux compartiments du ballon, de marqueurs (6) opaques aux rayons X permettant de suivre sa progression, hors de la gaine d'introduction, à l'intérieur du corps humain.

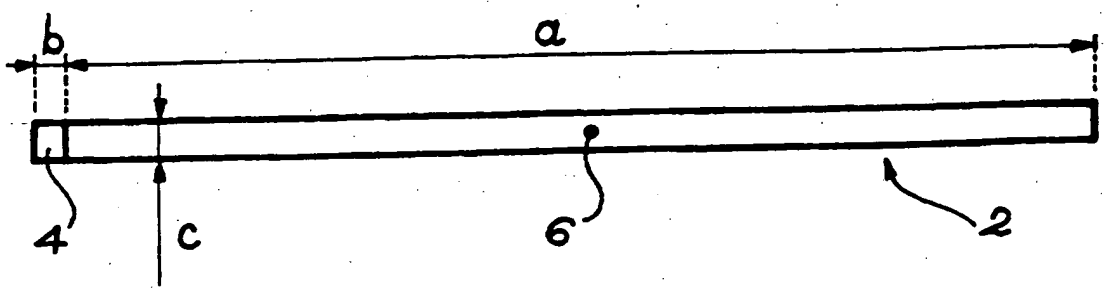

FIG. 1

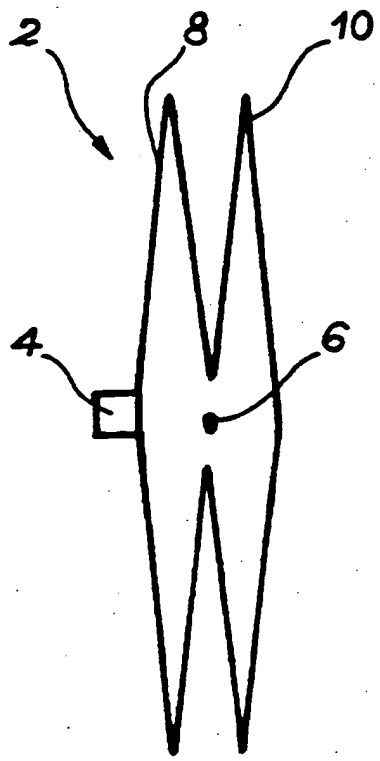

FIG. 2

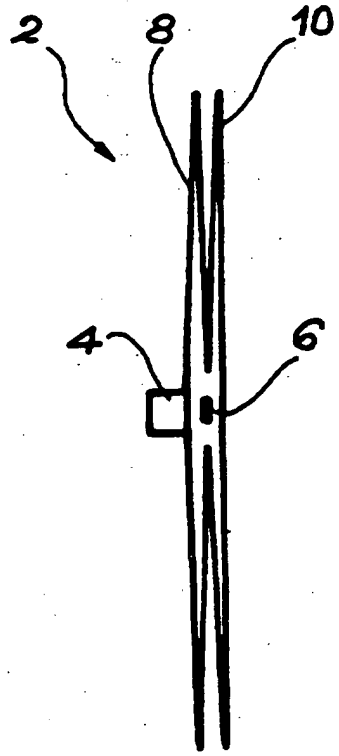

FIG. 3

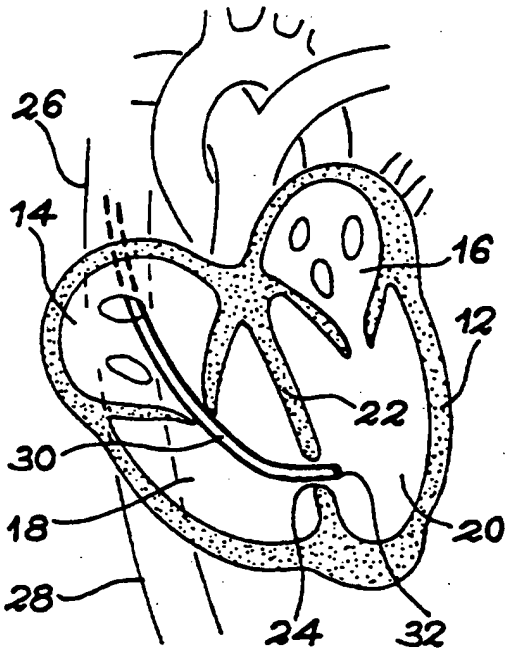

FIG. 4

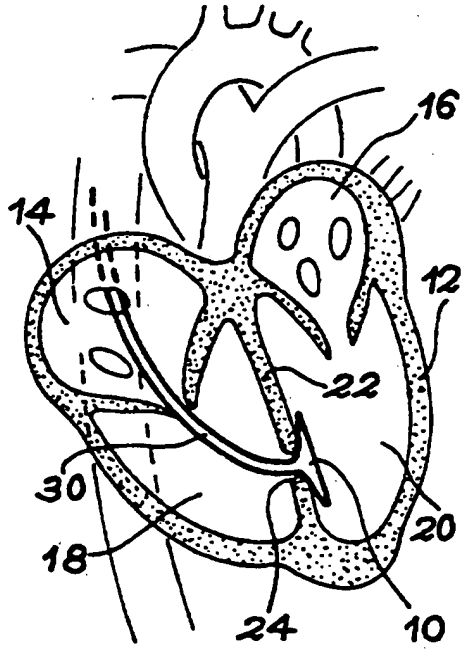

FIG. 5

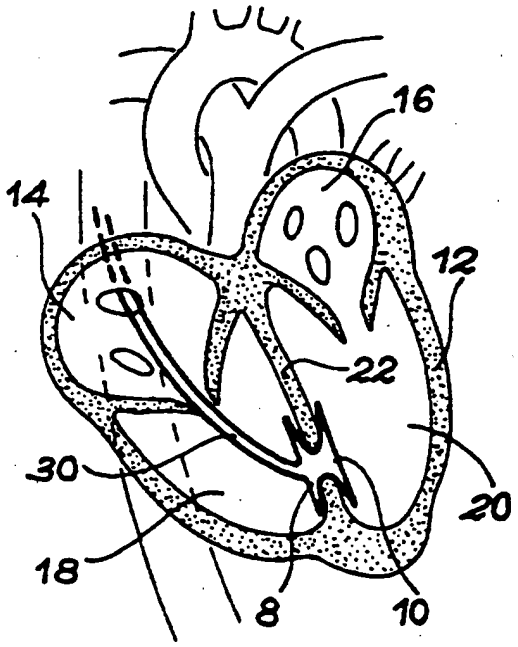

FIG. 6

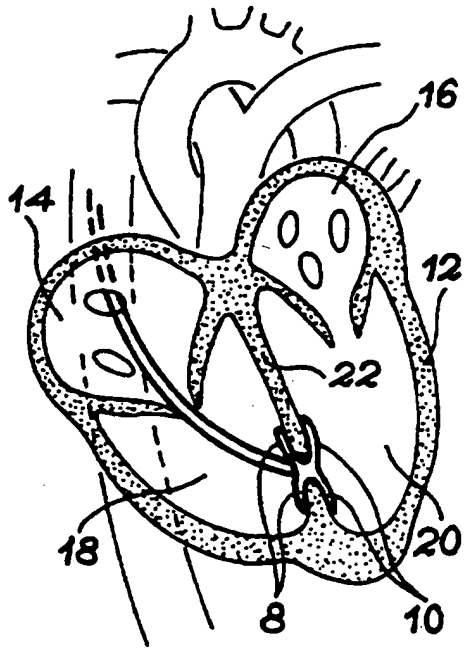

FIG. 7

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établi sur la base des dernières revendications déposées avant le commencement de la recherche

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N° d'enregistrement national

FA 494040
FR 9315565

DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	Revendications concernées de la demande examinée
A	US-A-4 836 204 (LANDYMORE) * colonne 2, ligne 47 - colonne 3, ligne 10; figures 1,8-14 *	1
A	US-A-3 874 388 (KING) * abrégé; figures 9A-9K *	1
A	US-A-4 007 743 (BLAKE)	
A	WO-A-93 13712 (REGENTS OF UNIV. OF MINNESOTA)	

DOMAINES TECHNIQUES RECHERCHES (Int.Cl.5)

A61B

Date d'achèvement de la recherche: 30 Août 1994

Examinateur: Papone, F

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A5R
F2N
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(54) Medical instrument for removing foreign bodies

(57) This invention relates to a medical instrument for the removal of foreign bodies out of physiological channels, such as ureters, arteries, bronchi and suchlike, having a flexible tube 1 for insertion into the physiological channel involved, said tube having an operating element 5 at its operator end and an expandable, element 6 at its insertion end, said expandable element being affixed at one end to the end of the tube 1 and at the other end to the end 8 of a controlling cable 4 and which via the controlling cable 4 which passes through the tube and which is connected to the operating element can be expanded and collapsed. The expandable element comprises a tube section made of a woven fabric or a braided fabric, the threads of which are spaced one from the other and which take an approximately screwthread-like course when the element is in the collapsed state. After insertion into the physiological channel, the element is expanded, it remaining permeable to fluids, but bearing foreign bodies with it on removal.

Fig. 1

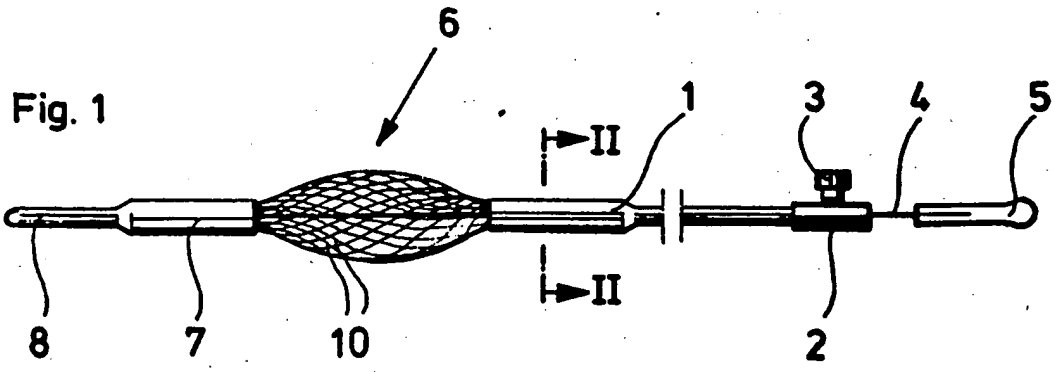

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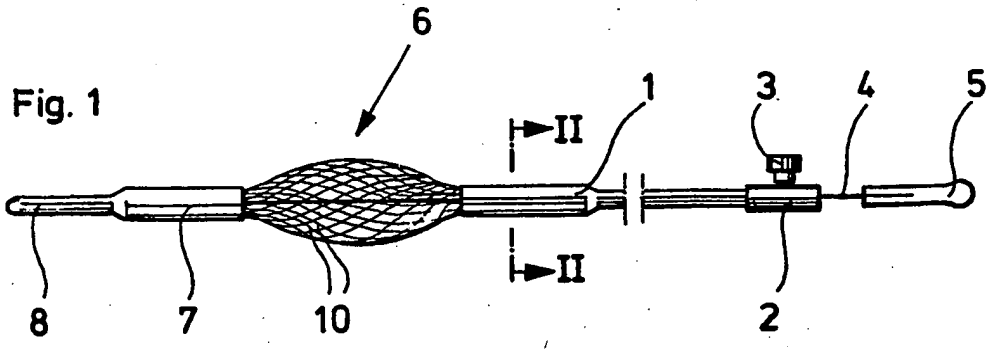
Fig. 1



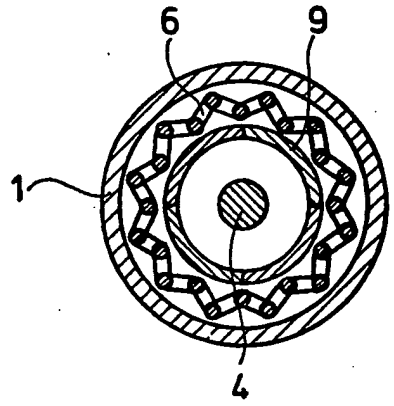


Fig. 2

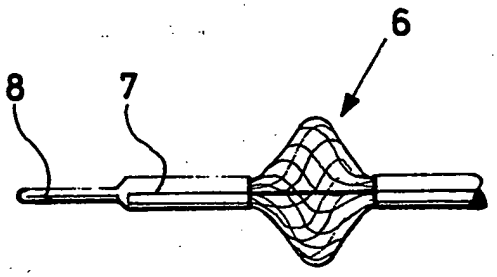


Fig. 3

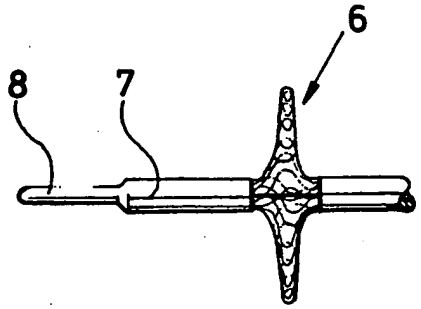


Fig. 4

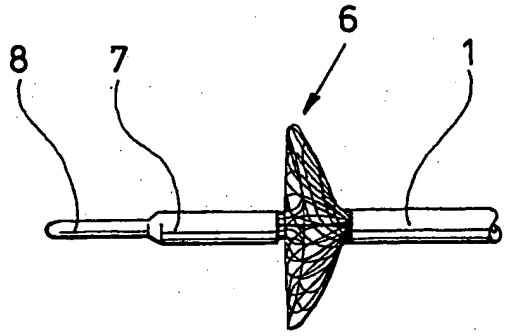


Fig. 5

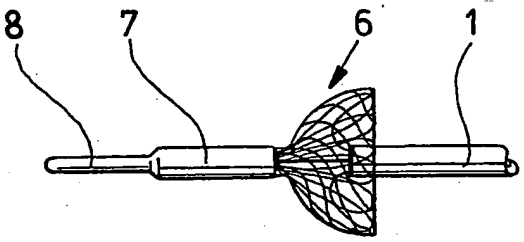


Fig. 6

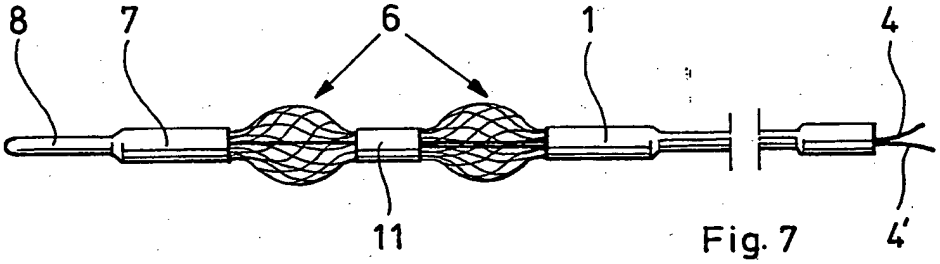


Fig. 7

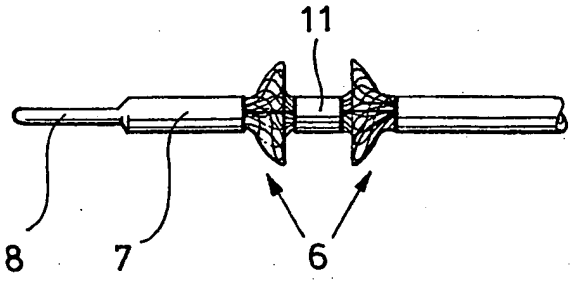


Fig. 9

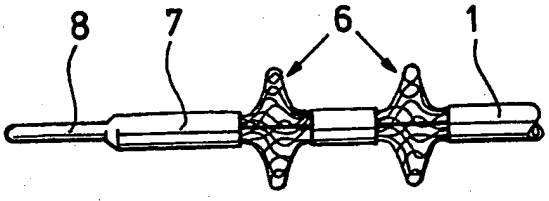


Fig. 8

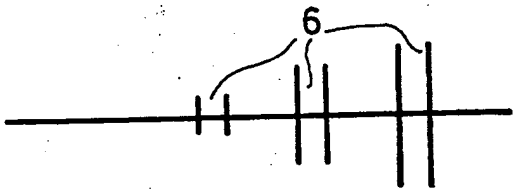


Fig. 10

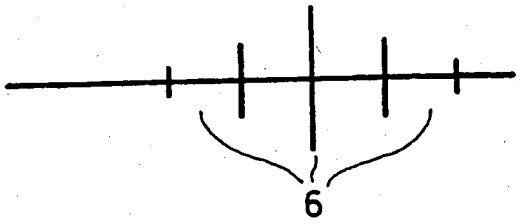


Fig. 11

SPECIFICATION

Medical instrument

The invention relates to a medical instrument for the removal of bodies out of physiological channels, such as ureters and biliary ducts, arteries, veins, bronchi, trachea and oesophagus and the like, which comprises a flexible tube for insertion into the physiological channel involved, the said tube having an operation element at its operator end and an expandable elastic element at its insertion end, the said elastic element being attached at one end to the tip of the tube and at the other to one end of a controlling element, and which is expanded and collapsed by means of the controlling element which passes through the tube and is connected to the operating element.

Similar instruments in the form of fishbone extractors have been known for many decades. These well-known fishbone extractors comprise a tube, through which a flexible rod is passed which is provided with a ring at its operator end. The operator end of the tube is provided with a handle. At the insertion end of the tube, a ring of hog's bristles arranged in the longitudinal direction, that is, along surface lines, is attached, the ends of the said bristles being bound together and affixed to the end of the flexible rod passing through the tube. For the facilitation of the introduction of the instrument, a small, spherical piece of sponge or a rounded rubber or metal head is affixed to the free end. By applying traction to the ring-shaped operating element, the practically stretched hog's bristles, which are only slightly curved outwards and form a kind of tube, are bent and, in consequence, more strongly curved outwards until they form a sort of sphere. In consequence of this operation, the fishbone to be removed from the oesophagus becomes graspable and can be captured between the hog's bristles and removed, removal being effected by complete or partial release of the operating element, thus effecting the relaxation of the hog's bristles and their resilient return to an original shape. (Rüsch-Katalog of 1910, pages 48, 49).

Further, an instrument for the removal of foreign bodies out of physiological channels is also known (DE–PS 1099126), which comprises a flexible small-bore tube, through which a controlling element is passed, the said controlling element being provided with an operating member at the operator end. At the insertion end, a bushing is attached to the controlling element, into which bushing a number of spring wires wound in the form of screw threads are inserted, the free ends of which engage in a pointed-arch-shaped head, in which they are fixed. By applying traction to the operating element, the spring wires are drawn into the tube. After insertion of the instrument into the physiological channel, the operating element, which is located at a distance from the operator end of the tube, is shifted towards this end of the tube, with the result that the spring wires emerge from the end of the tube and, owing to their springiness, form themselves into a basket which, in profile, takes up an onion-like form, the said basket being capable of accepting a kidney stone or other foreign body. By partially pulling back the operating element, the basket is caused to narrow and made to close round the foreign body which can subsequently be removed by withdrawing the tube.

Gall stone extractors are also known (Rüsch-Katalog No. 328000), which comprise a flexible tube, at the insertion end of which a balloon is affixed, the said balloon being inflatable via the tube by employing a Luer Lok syringe or something similar. The extractor is introduced into the physiological channel, for example, into the ureter, until the balloon is located beyond the stone to be removed. Following the inflation of the balloon, the stone is released by the dilatation thus caused and can be removed by withdrawing the extractor.

Finally, a universal embolus and thrombus extractor is also known (Rüsch-Katalog No. 327000), which is essentially identical in its construction to, differing merely in its dimensions from, the previously mentioned gall stone extractor. It serves to remove thrombi and emboli from arteries or veins.

The objective of the present invention is to provide an improved, universally employable instrument for the removal of bodies out of physiological channels, which can be employed by the physicians without any problem.

This objective has been achieved by this invention starting from a medical instrument of the type mentioned initially by the use of an expandable element constituted by a woven-fabric or braided-fabric tube section, the individual threads of which are spaced, one from the other, and which, when the element is in the collapsed state, are twisted, partially to the right, partially to the left, in an approximately screwthread-like manner.

In this (viewed retrospectively) surprisingly simple manner, it has been possible to produce a universally employable medical instrument for the removal of foreign bodies out of physiological channels, which, depending upon its dimensions, can be employed to advantage for a wide range of different purposes. On the one hand, it can serve as a fishbone extractor and can equally be used for the removal of gall stones and the like. In the latter case, a particular advantage resides in the fact that neither the capture of the stone in a basket is required—a manouvre requiring considerable luck and skill—nor is there any risk of the balloon of the extractor being burst

by a sharp-edged stone. In the case of the instrument of the invention it is, namely, of advantage that, in consequence of the expansion of the expandable element, an umbrella is formed which not only dilates the physiological channel and thus results in an easier release of the stone, but which also manifests no tendency to wedge the stone in the acute angle between the balloon and the wall of the channel, but rather, in the manner of a snowplough, pushes the stone before it. In consequence, the handling of the instrument of the invention is extremely simple, with the result that the chances of achieving success with the manouvre are very much increased and the risks to the patient considerably reduced. However, the instrument of the invention is also equally suitable for the removal of thrombi and emboli out of veins and arteries, the already mentioned snowplough effect being of great advantage. Finally, a further advantage resides in the fact that the collapsed element manifests a relatively small diameter, while the expanded element manifests a multiply enlarged diameter. The unexpanded element is very elastic and the expanded element surprisingly rigid and resistant to distorsion. Moreover, in some applications an additional advantage lies in the fact that the expandable element, whether in the collapsed or expanded state, manifests a grid-like structure, which permits the passage of fluids.

The introduction end of the instrument can take various forms. For example, the introduction end can be formed by a fusion of the threads forming the woven or braided section of the tube. The end of the controlling element passes into, and is attached to this fused head, for example by melting. In the case of other preferred embodiments of the invention, however, a small-bore tube having a closed, rounded free end, is pushed over the insertion end of the controlling element and flexible tube section. Both embodiments have the advantage of permitting the easy introduction of the instrument in the form known from catheters and familiar to every physician.

As the controlling element, preference is given to a spring wire. Such a wire is, on the one hand, adequately stable while, on the other hand, being sufficiently formable. In addition, it offers the advantage of conferring X-ray opaqueness on the medical instrument, which means that the physician can establish the depth of insertion of the instrument and the course it has taken, or the location of the insertion end within the body of the patient.

The tube can be made of various different materials. Preferentially, it is made of a plastic material. In a more advanced embodiment of the invention, a helical spring is inserted to stiffen the tube and provide a guideway for the controlling element. Nevertheless, the tube is elastically formable. Its construction is comparable to the outer sheathing of a Bowden cable.

In particular in the case of a relatively long and very thin instrument, such as is required, for example, for the removal of thrombi and emboli, the manufacture of the instrument can give rise to difficulties. Therefore, in the preferred versions of the invention, the tube is constructed in the form of a shrink-down plastic tubing. In consequence of its enlarged diameter, this tubing can be easily pushed over the helical spring sheathing, to which, after appropriate heating and resulting shrinking, it approximates tightly and virtually jointless.

In a preferred embodiment of the invention, the medical instrument is provided with more than one expandable element and the individual expandable elements are arranged at a distance from one another. This embodiment of the invention has considerable advantages. For example, it makes it possible to capture a foreign body between two expanded elements as in a cage, and to push it along the physiological channel. During this process the leading expanded element, by virtue of its snowplough effect, removes other depositions or bodies located within the channel which might make the removal of the foreign body in the cage difficult or, by conglomerating with the foreign body, even prevent is removal altogether. Finally, when expanded, the expandable elements can manifest differing diameters, which, in particular, can increase progressively in one direction. This feature, too, can lead to a more reliable and certain action of the instrument of the invention, when the elements are appropriately dimensioned.

The constructive design of the instrument with several expandable elements, can take varying forms. For example, a separate controlling element can be associated with each expandable element, each controlling element being provided with its own separate operating element. This design, however, both requires a relatively complicated construction—and thus is expensive in its manufacture—and also results in a relatively complicated form of application. In the preferred embodiments of the instrument of the invention, therefore, a stiff section of tube is provided between the expandable elements, and the expandable elements are expandable by means of a common controlling element which is connected to the expanded element closest to the insertion end. The traction applied to the introduction end by the controlling element acts, via the nearest expandable element and the following section of tube, upon the next expandable element and causes all the expandable elements to become expanded in the same manner.

In preferred embodiment of the invention, the woven or braided material has a mesh size which is some three to ten-fold greater than

the thickness of the threads forming the woven or braided fabric. Such a relationship of dimensions results in the expandable element having good qualities of formability coupled with an adequate permeability and, on the other hand, an adequately small mesh for the removal of even relatively small bodies or foreign bodies. The small mesh of the expanded element results, in particular, from the fact that the "umbrella" created by expansion, comprises two woven or braided layers in contact with each other, with the result that the effective mesh size is reduced. The relatively large mesh size of the unexpanded element offers the advantage of high flexibility. In the unexpanded element, the mesh spaces adopt a rhomboid shape, of which the diagonal parallel to the longitudinal direction of the instrument is very much greater than the diagonal arranged tangentially to the tube. The individual threads run substantially along a helical line, account having to be taken of the fact that the tube section has no constant diameter in the longitudinal direction, but manifests a diameter which increases somewhat from the ends towards the middle. When expanding the element, the individual threads move relative to one another, and the length ratio of the two diagonals of each rhombic shape alters until, in a mean position, the rhombic shapes have become substantially square. On being further altered in shape, the expandable element forms a circular disc comprising two layers of material under initial tension, the centre of the disc merging, funnel-like, into the neighbouring end of the tube. The funnel adopts the form of the whirlpool seen at a water-drain hole. In this expanded position, the threads adopt a substantially circular contour in the region in which they form the disc. The form of the mesh spaces can deviate from the form just described if other fabric weaves are used as will be described in more detail later.

In preferred embodiments of the invention, the weave or braid consists of plastic-material threads, in particular, solid polyester, polyamide or PVC threads. The use of solid threads in preference to spun or braided threads provides the advantage of improved mobility of the threads with respect to one another, with the result that the change of shape and return to the original shape of the expandable element is favoured.

However, as in other embodiments, the woven fabric or braided fabric can be made also of a natural material, in particular silk, linen or cotton. (silk is obtained from the insides of the silkworm).

The weave of the woven fabric or braided fabric can take various forms. For example, either a plain weave or a satin weave can be employed. In the preferred embodiment of the invention, however, the woven fabric or the braided fabric is of twill weave and, in particular is a K^2_2 weave. This weave has proved particularly successful, since it permits ready deformation of the expandable element and, on the other hand, provides a good returning force. In addition, at the same time, favourable mesh widths can be realized.

The non-expanded element, preferably manifests the same shape as the unexpanded fishbone extractor, that is, the shape of a spindle or a tube having a somewhat greater diameter in the middle. Nevertheless, without there being any change in the outer appearance of the unexpanded element, it is possible for the expanded element to have differing shapes. In general, it takes the already described shape of a disc ending on either side in a funnel. The expanded element is symmetrical to a plane passing through the middle of the disc, the plane being traversed centrally and perpendicularly by the tube and the controlling element. In other preferred embodiments of the invention, however, the expandable element is, an expansion, arranged unsymmetrically with respect to a transverse central plane, and in the expanded state takes the form of an opened umbrella. Thus, the two contacting or neighbouring surfaces of the braided or woven fabric which, in the expanded state extend from a circular outer common margin, are not domed in opposing directions, but in one and the same direction. In this condition, the open side of the dome or vault can face the insertion end. Preferably, however, the expanded element presents a concave umbrella shape, the opening of which faces the operator end. This has the advantage that, when removing foreign bodies, the latter show a tendency to move towards the middle of the umbrella, that is, away from the wall of the physiological channel. This not only facilitates the removal procedure, but also, for example, prevents any damage being done to the wall of the physiological channel during the removal of sharp-edged stones from relatively narrow channels. Thus, the expandable element spread into an umbrella-like shape not only dilates the channel locally and reversibly, but, at the same time, also ensures that the foreign body is kept at a distance from the wall of the channel.

The realization of the expandable element in such a way as to result in an umbrella-like shape in the expanded state, is effected by a type of mechanical memory of the woven-fabric or braided-fabric tube section. This mechanical memory can, for example, be induced by means of a constrained mechanical deformation during the initial expansion. However, a thermal treatment can also be carried out either in place of or additional to this mechanical treatment. It would also be possible to produce the braided fabric using yarn or threads tapering in one direction, so that in this manner a preferential deformation might

be achieved. Admittedly, the manufacture of a braided fabric employing tapering yarn or threads would be very complicated and expensive, so that the previously explained methods are preferably employed.

Further details and improvements of the present invention will be obvious from the following description and the drawing showing embodiments explained herein, read in conjunction with the claims. The figures are as follows:

Figure 1 a side view of an instrument of the invention with the element in the non-expanded condition,

Figure 2 a cross-section taken along line II–II of Fig. 1,

Figure 3 the instrument shown in Fig. 1, with the element partially expanded,

Figure 4 the instrument shown in Fig. 1, with the element completely expanded,

Figure 5 an instrument which, with unexpanded elements, is indistinguishable from the instrument shown in Fig. 1, with expanded element,

Figure 6 an instrument with expandable element expanded to another shape,

Figure 7 an instrument with two non-expanded, expandable elements,

Figure 8 the instrument shown in Fig. 7, with the elements expanded,

Figure 9 an instrument similar to that shown in Fig. 8, but with the elements unsymmetrically expanded, and

Figures 10 and 11 schematically represented elements with numerous elements of different diameters.

The representation in the drawings is, in part, enlarged, in order the better to represent details.

The medical instrument illustrated in Fig. 1 comprises a flexible tube, 1, which is preferably made of plastic material and whose diameter can be between about 2 to 3 mm and 50 to 100 mm, depending upon the particular application. At the operator end of the tube, 1, a locking means, 2, is provided, which comprises a bushing with a radially arranged screw, 3, with the aid of which a wire passing through the bushing and serving as a controlling element, 4, can be locked. At the free end of the controlling element, 4, there is an operating element, 5, which, for example, takes the form of a section of tubing or a small operating knob. At the opposite end of the tube, 1, an expandable element, 6, is arranged comprising a tube-like section made of woven fabric or braided fabric, one end of which is introduced into the end of the tube, 1, whereas the opposite end is introduced into, and affixed to, a hollow head piece, 7, the distal section of which is tapered, and the tip of which is rounded and closed off. Within the tube, 1, and also within the section of the expandable element, 6, located within the tube, 1, there is arranged a helical spring, 9, (Fig. 2), the closely neighbouring windings of which form a sort of tubular guideway similar to that seen in the Bowden cable. The controlling element, 4, which takes the form of a wire, extends to the head piece, 7, in which its end is affixed.

The woven-fabric or braided-fabric tube section that makes up the expandable element, 6, consists of twill-woven yarn 10, a $K\frac{2}{2}$ weave being preferably used. In this weave, each warp yarn passes over two filling yarns and then under two filling yarns while, vice versa, the filling threads pass in the same manner over two warp yarns and under two warp yarns. Neighbouring warp and filling threads are displaced with respect to each other by one thickness. The yarns, 10, each comprise a single thread, that is, they are not made up of a number of twisted, braided or woven or tangled threads. Preferentially, they are made of artificial material and manifest as smooth a surface as possible, so that, when the expandable element, 6, is made to change its shape, they can move relative to one another. However, the yarns, 10, may also be made of natural fibres or silk.

If, by pulling on the operating element, 5, the controlling element, 4 is moved relative to tube, 1, that is, if the controlling element, 4 is drawn out of the tube, 1, the end of the controlling element, 4, takes the head piece with it, so that the expandable element, 6, is expanded until it has attained approximately the form shown in Fig. 3. During this process, the shape of the mesh formed by the threads, 10, changes. If the head piece, 7, is further moved towards the tube, 1, the configuration of the expandable element, 6, represented in Fig. 4 is finally attained, the outer diameter of which is two- or several-fold the diameter of the non-expanded element, 6, (Fig. 1).

When employed, the instrument is inserted with the end, 8, leading into the physiological channel, for example, via the urethra and bladder into the ureter, and advanced until the expandable element, 6, is located at the far side of the foreign body to be removed, for example, a gall stone or a kidney stone. During this process, the position of the instrument can be monitored by X-ray means, since both the helical spring, 9, and the wire forming the controlling element, 4, are clearly imaged. Finally, by applying traction to, and then releasing, the controlling element, 4, for as many times as might be necessary, the expandable element, 6, is expanded and collapsed in order to release the stone from the wall of the physiological channel. Finally, with the element, 6, in the expanded position, the instrument is withdrawn, the expanded element, 6, bearing the stone with it.

For the removal of thrombi, that is clots of blood, or emboli, that is, droplets of fat, foreign bodies or the like, out of veins or arteries, the instrument is introduced into the

appropriate vessel until the end, 8, penetrates through the thrombus or embolus and the expandable element, 6, is located beyond the embolus. Finally the element, 6, is expanded until it is in contact over its circumference with the wall of the vein, the latter being dilated during the process, and then the instrument is withdrawn, the expandable element, 6, bearing the embolus with it.

By appropriate mechanical, thermal or chemical pre-treatment of the expandable element, 6, it is also possible to achieve expanded configurations such as are shown in Figs. 5 and 6. In particular, the arrangement shown in Fig. 6 is especially suitable for the removal of foreign bodies, since with the shape of this embodiment, when the instrument is withdrawn, the body to be removed is collected up as in a basket, the circumferential wall serving as a scraping means which loosens any particles adhering to the walls of the channel and causes them to move into the basket.

Multiple arrangements as shown in Figs. 7 to 11 are also possible. In such embodiments, the expandable elements can take on varying expanded forms and also differing expanded diameters.

A substantial advantage of the instruments of the invention is the fact that they are highly universal in their application, and need to be matched to the physiological channel involved, only with respect to their dimensions, it also being possible to effect such a matching by appropriately adjusting the degree of expansion of the expandable element. In many cases, the grid-like lattice structure of the expanded element, 6, is also of advantage, since it permits the passage of fluids through it.

The instruments of the invention also make it possible to remove thrombi and emboli located at places that are difficult of access. They also make it possible to do away with the insertion of filters into veins, for example the inferior vena cava, the use of which has occasionally led to complications owing to the fact that the inserted umbrella has come away from its achorage and migrated through the vein to the heart and through the heart into the pulmonary artery.

The Mobin-Uddin filter employed, for example in this case, then had to be removed by surgical means. If, instead of using such a filter, a vena cava occlusion is carried out with the aid of a balloon, it can be observed that, over the course of several months, the balloon collapses, and it is not certain whether it is then held in situ by the vein. But, also in this case, a permanently in-dwelling foreign body remains in the vein, which can give rise to disorders. The balloon cannot be made of silicone rubber, since this material is not adequately stable mechanically (tear propagation

great a permeability for gases. For this reason, it must be made of latex, to which softening agents and other additives are admixed which can separate out again and migrate through, or distribute themselves throughout, the body of the patient. In contrast, the instrument of the invention can also be employed in such cases and removed again after several days. Such applications are found, for example, following surgical operations, after accidents or in the case of patients confined to bed over lenthy periods of time, in whom thrombi frequently form, in particular in the veins of the legs. Such thrombi, when they become detached, pass via the heart into the arteries of the lungs, where they cause embolisms. In consequence of this, if such an embolism does not lead to death within a matter of seconds, larger or smaller areas of the lungs are cut off from the circulation and an overloading of the right heart, pneumonia and the like occur. Treatment of these pulmonary emboli is possible by means of lysis with the aid of Streptokinase at the very early stage. Further thrombi can, however, become detached within the deep veins of the legs and the veins of the pelvis, which thrombi can lead to further embolisms. In general, it is not possible to reduce the clottability of the blood in freshly operated-on patients, since, then, the surgical wounds would start to bleed again. The treatment with Streptokinase can, however, be carried out only over a few days since then, an anti-reaction of the body eliminates the effect of the Streptokinase again. Thus, a patient must be protected from further emboli both during the lysis of a pulmonary embolus and also subsequently, and this is why the already mentioned Mobin-Uddin filter or a balloon has been used to occlude the vena cava. By employing one of the instruments of the invention, and with appropriate expansion, which can be fixed by locking the controlling element, 4, with the aid of the screw, 3, the above-mentioned problem can be solved in a simple manner. The expanded element is permeable and blood can continue to flow through the vein. Any thrombi that might be carried along by the blood, are captured by the expandable element and, when after a number of days the danger is past, the instrument, together with any captured thrombi, can be removed again, unless no lysis or breakdown has been achieved by means of anti-clotting agents such as, for example, heparin or Streptokinase. Thus, no foreign body, which itself could represent an endangerment or could give rise to complications, remains for any lengthy period of time within the body of the patient. The embodiments illustrated in Figs. 10 and 11, serve to produce a gradual dilatation of the physiological channel. On the basis of the increasing and, possibly, again decreasing series of di-

dilatation and, where applicable, re-narrowing of the channel can be achieved.

It is also possible, but not illustrated in the drawing, to pass a further thin tube or a thin length of tubing, through the flexible tube, 1, the thin tube or length of tubing terminating at one of the elements, 6, or in the head piece, 7. Through this thin tube or thin length of tubing, fluids or gases can be introduced or removed. Thus, for example, stone-dissolving or thrombolytic agents can be this manner be introduced. Equally, specimen of the patient's own body fluids can be obtained from the side of application of the expandable elements and, for example, employed for analytical purposes.

It goes without saying that the invention is not restricted to the embodiment examples represented here, but that deviations of these are also possible, without exceeding the framework of the invention. In particular, individual characteristics or features of the invention can be employed either alone or combined severally.

CLAIMS

1. A medical instrument for the removal of foreign bodies out of physiological channels, such as ureters and biliary ducts, arteries, veins, bronchi, trachea and oesophagus and the like, which comprises a flexible tube for insertion into the physiological channel involved, the said tube having an operating element at its operator end and an expandable elastic element at its introduction end, the said elastic element being attached at one end to the tip of the tube and at the other to one end of a controlling element, and which is expanded and collapsed by means of the controlling element which passes through the tube and is connected to the operating element, the expandable element comprising a woven-fabric or a braided-fabric tube section.

2. A medical instrument in accordance with claim 1, wherein a head piece having the form of a small tube with a closed, rounded free end is fitted over the insertion end of the controlling element and the expandable element.

3. A medical instrument in accordance with claim 1, wherein at the insertion end the threads of the woven-fabric or braided-fabric of the tube section comprising the expandable element are fused one with the other and that at the fused head, the end of the controlling element is affixed, for example, by melting.

4. A medical instrument in accordance with any one of claims 1 to 3, wherein a spring wire is employed as the controlling element.

5. A medical instrument in accordance with any one of claims 1 to 4, wherein the tube is stiffened by means of an inserted helical spring which forms a guideway for the controlling element.

6. A medical instrument in accordance with one of the previous claims, wherein the tube is formed from a shrink-on tube.

7. A medical instrument in accordance with one of the previous claims, wherein more than merely one expandable element is provided, and the individual expandable elements are provided in spaced arrangement.

8. A medical instrument in accordance with claim 7, wherein between the expandable elements a rigid tube section is provided, and the expandable elements are expandable by means of a joint controlling element which is connected to the expandable element in closest proximity to the insertion end.

9. A medical instrument in accordance with claim 7 or 8, wherein the expandable elements manifest, in the expanded state, varying and increasing diameters in one direction.

10. A medical instrument in accordance with any one of the preceding claims, wherein the woven fabric or braided fabric forming the expandable element manifests a mesh width which is three to ten times the thickness of the threads forming the woven fabric or the braided fabric.

11. A medical instrument in accordance with any one of the preceding claims, wherein the woven fabric or the braided fabric is made of threads or yarn of a plastic material, for example, solid polyester, polyamide of PVC threads or yarn.

12. A medical instrument in accordance with any one of claims 1 to 10, wherein the woven fabric or braided fabric is made of a natural material, for example, silk, linen or cotton.

13. A medical instrument in accordance with any one of the preceding claims, wherein the woven or the braided fabric is made in twill weave, for example, as $K\frac{2}{2}$ weave.

14. A medical instrument in accordance with any one of the preceding claims, wherein the expandable element on being expanded, distorts unsymmetrically with respect to a transverse central plane of the controlling element and, in the expanded state, manifests the shape of an open umbrella.

15. A medical instrument in accordance with claim 14, wherein the expandable element forms a concave umbrella shape open towards the operator end.

16. A medical instrument, substantially as herein described with reference to and as illustrated in the accompanying drawings.

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